

Serial No. 10/688,694  
Amendment After Final Under 37 CFR §116  
Response to Final Rejection dated January 25, 2006

### **REMARKS/ARGUMENTS**

Reconsideration of the rejections set forth in the above-identified Final Rejection is respectfully requested.

The thoroughness of the review of this application by Examiner Daniels is appreciated. With the foregoing amendment and the following remarks, it is believed that the rejections set forth in the Final Rejection have been overcome.

#### **I. The 35 USC §112 Rejection of Claim 28**

Claim 28 was rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. It was stated that the limitation "at least about 1.5:1" did not appear to have support in the specification as filed.

Applicant respectfully submits that there is ample support in the specification as filed for such language. See, for example, page 2, line 30 and page 3, line 14. However, in order to advance the prosecution of the application claim 28 is being amended to state that the stretch ratio is from about 1.5:1 to about 5:1. Ratios of "from about 1.5:1 to about 5:1" are specifically disclosed in the specification at page 6, line 7, for example. Accordingly, it is respectfully submitted that claim 28 fully complies with 35 USC §112 and that the rejection on such grounds should be withdrawn.

#### **II. The 35 USC §103 Rejections**

##### **A. Summary of the Invention**

To briefly summarize Applicant's invention, it relates to a method of making oriented films of polychlorotrifluoroethylene (PCTFE) polymers. These films have

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excellent transparency and moisture barrier properties and have been used in many demanding applications, including pharmaceutical blister packaging and in the manufacture of electroluminescent structures such as lamps.

Such films are typically manufactured by a film extrusion process, wherein molten PCTFE resin is cast into the form of a film, which is subsequently wound up. Stretching of such film is done as an off-line process.

Stretched films of PCTFE resins are known, for example, from U.S. Patent 4,544,721 to Levy. However, Levy requires that the film be substantially amorphous before it is stretched and that stretching be conducted within a narrow stretch zone. Such a process results in reduced line speeds and hence reduced manufacturing efficiencies. Applicant has found that PCTFE polymer films can be oriented in their crystalline state to provide films with excellent water vapor barrier properties while maintaining their other desirable mechanical and chemical properties.

One advantage of the process of this invention is that the orientation is simpler and can be done in-line with the manufacture of the film. The resultant film has a very low water vapor transmission rate, which is less than about 20% of the water vapor transmission rate of comparable film that is unoriented. Applicant's method comprises orienting a PCTFE film which has a crystallinity prior to orientation in the range of about 10 to about 45%, more preferably in the range of about 15 to about 35%. It is respectfully submitted that the claimed invention is not suggested or disclosed in the applied prior art and that claims 1, 3-12, 14-21 and 23-25, 28 and 29 are patentable and should be allowed.

The rejections of the claims as set forth in the Final Rejection are respectfully traversed. It is acknowledged that the 35 USC §102 (b) rejection of the claims as being anticipated by Mizuno has been withdrawn.

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B. Claims 1 and 3-12

Claims 1 and 3-12 now stand rejected as being obvious over Mizuno in view of the newly cited Choy and Khanna articles. Reconsideration and withdrawal of this rejection are respectfully requested.

It was acknowledged in the Final Rejection that "Mizuno does not explicitly teach the limitation that the film has a crystallinity of from about 10 to about 45%" and that "Mizuno clearly suggests and finds it desirable to quench the sheet after extrusion to suppress crystallinity, which facilitates the stretching thereof". Applicant agrees with this summary of the teaching of Mizuno. The question then is whether one skilled in the art would find it to be obvious to start with a film that has a crystallinity level of from 10 to 45% (claim 1) or 15-35% (as stated in claim 3) before the stretching step. The Final Rejection relies on the disclosures of two secondary references to suggest that any type of quenching will inherently result in a crystallinity level within the claimed range. It is most respectfully submitted that this supposition is incorrect.

Khanna was relied upon as teaching that when PCTFE samples are quenched, they contain 15 to 50% crystallinity as determined by differential scanning calorimetry (DSC). It was also stated that Choy teaches that quenching a sample produces a crystallinity of 39%. These references are relied upon as teaching that crystallinity can only be suppressed to a level of 15 to 50%.

The problem with this assumption is that Khanna and Choy are not dealing with thin films as are Mizuno and Applicant. The film of Mizuno has a thickness of at most 100  $\mu\text{m}$  (= 3.9 mils), and preferably in the range of 20 to 70  $\mu\text{m}$  (= 0.8 to 2.8 mils); see column 7, lines 21-24 of Mizuno. The films of Applicant's invention are in the range of 0.1 to 15 mil (= 2.5 to 381  $\mu\text{m}$ ), preferably from 0.2 to 5 mils (= 5.1 to 127  $\mu\text{m}$ ). Thus the films of both Mizuno and Applicant are thin films.

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On the other hand, both Khanna and Choy refer to a much thicker plaque upon which a crystallinity measurement is made. In Khanna, molded plaques were used which were molded to a thickness of 1.25 mm (= 50 mils); see page 2010 of Khanna, right column. Likewise in Choy, a thick plaque was also used, with a thickness of 1.5 mm (= 60 mils); see page 569, left column. Thus, the levels of crystallinity reported by both Khanna and Choy are for thick plaques, which have a thickness of at least an order of magnitude greater than the thickness of the thin film of Mizuno. It is respectfully submitted that one skilled in the art would not interpret the teachings of Khanna and/or Choy as meaning that the thin film of Mizuno must have a high crystallinity level before stretching and must not be amorphous. In fact, this goes against the express teaching of the Levy patent mentioned above, which will be discussed below.

A thick plaque acts differently from a thin film when it is quick quenched. The thicker material will have a higher crystallinity; its surfaces may be amorphous but its center will be crystalline. Since the center is thicker than the surfaces, the average crystallinity of the sample will be higher. In contrast, a thin film when quick quenched will have an amorphous structure.

Referring back to Mizuno, this reference requires that a high molecular weight PCTFE polymer be employed for orientation. If the melt flow rate of the polymer is greater than  $2 \times 10^{-1}$  cc/sec then the stretched film is liable to be broken due to too low a molecular weight (see column 5, lines 48-60). Indeed, Mizuno goes on to state that "a lower molecular weight promotes crystallization so that it is becomes difficult to obtain a stock sheet having a low crystallinity, thus making the stretching difficult". (column 5, lines 60-63). Mizuno then goes on to state that the extruded sheet is cooled or quenched "to suppress crystallization of the PCTFE stock sheet and facilitate stretching thereof" (column 6, lines 2-5).

Accordingly, Mizuno's invention relates to the use of high molecular weight PCTFE resin and recognizes that a lower molecular weight resin can promote undesirable

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crystallization. This, it is respectfully submitted, is a clear indication that the extruded film of Mizuno has a low crystallinity as specifically intimated at column 5, line 62. Mizuno wants to have a low crystallinity in order to avoid difficulties in stretching. Clearly, Mizuno distinguishes between a crystalline film prior to stretching and an amorphous (or low crystallinity) film prior to stretching. It is respectfully submitted that one skilled in the art would recognize that the film of Mizuno prior to stretching is an amorphous film. This is in distinction to the crystalline film that is employed in Applicant's method.

The use of an amorphous PCTFE as the starting point in Mizuno's process is supported by the prior teaching of Levy (USP 4,544,721) which is discussed in the instant specification. Levy specifically states that the "film to be stretched must be a substantially amorphous film in order to obtain good oriented film" (see column 2, lines 54-55). Levy measures crystallinity by X-ray diffraction, and states that after stretching the film is semi-crystalline (see column 2, lines 59-60).

Thus, it was clearly recognized by those skilled in the art that the film prior to stretching must be amorphous. It is submitted that Mizuno is merely repeating what Levy had earlier presented to the art.

It is also important to mention the above-cited reference to Levy with regard to changing the nature of the film from substantially amorphous to semi-crystalline. This of course shows that the stretching operation does increase crystallinity. It is most respectfully submitted that this statement clearly rebuts the assumption set forth in Paragraph d) on page 14 of the Final Rejection wherein it is stated that "orientation would not, by itself, increase the percentage crystallinity".

It is thus respectfully submitted that although Mizuno does not specifically state the percent crystallinity of the film prior to stretching, such film is in fact amorphous, just like the film of Levy.

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The issue as proposed in the Final Rejection is whether the film of Mizuno is amorphous prior to stretching or must it be crystalline in view of the disclosures of Khanna and Choy. It is respectfully submitted that neither Khanna nor Choy properly modify the teaching of Mizuno to provide the important missing part in Mizuno, viz., a crystalline film that is then stretched.

Looking more particularly at the Khanna article, the purpose thereof is to suggest a glass transition temperature (T<sub>g</sub>) for poly(chlorotrifluoroethylene). Khanna is not at all concerned with processing of PCTFE films, much less stretching such films in their crystalline state. As mentioned above, Khanna makes plaques from PCTFE resin. These plaques are compression molded to a thickness of 1.25 mm (50 mils) and are either cooled in the press or quick quenched in ice-cold water. The molecular weight of the resin is what one skilled in the art would consider a standard molecular weight (one sample was 300,000 and the other 850,000 – see page 2011 left column). Khanna mentions that a quenched copolymer of 96% CTFE and 4% vinylidene fluoride has a crystallinity of about 15-20% (page 2013, left column), whereas the crystallinity of a PCTFE homopolymer that was tested to determine its T<sub>g</sub> was 30-50% (page 2012, right column). Khanna's suggestion of a T<sub>g</sub> for PCTFE only peripherally is related to the crystallinity of PCTFE material, and then only for thick molded plaques as opposed to thin films as in Mizuno.

It is respectfully submitted that one cannot make a leap from the crystallinity level determined by DSC on a thick plaque to the crystallinity level that would be in a thin film that is quenched. Rather, one skilled in the art would recognize that a thin film would have a much lower crystallinity under the same treatment conditions. Moreover, it is well known that the DSC test itself crystallizes a sample as it requires heating up of the sample. The basis of the rejection relying upon Khanna seems to be predicated on the belief that low crystalline PCTFE materials cannot be obtained when quenched.

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The Examiner's attention is respectfully directed to the attached article of Murthy, Khanna and Signorelli entitled "Crystallinities of Poly(Chlorotrifluoroethylene) and its Copolymers by Differential Scanning Calorimetry, X-Ray Diffraction, and Density Measurements", Polymer Engineering and Science, August 1994, vol. 36, no. 16, page 1254 et seq. (hereinafter Murthy). It is pointed out that the second author is the same Khanna as in the Khanna reference that is cited in the Final Rejection.

In this article, it can be seen that crystallinities in PCTFE polymers as low as 11% have been measured by X-ray diffraction (Sample J in Table 1, page 1255). On the other hand, the crystallinity level determined by DSC for the same sample was 22%, which is substantially higher than both the X-ray and density measurements. It is important to note that the low crystallinities in Levy ("substantially amorphous") were also determined by X-ray diffraction (XRD). Murthy tested the crystallinity of films that had a thickness of 75  $\mu\text{m}$  ( $\approx$  2.9 mils), for example, as opposed to the much thicker plaques of Khanna (which were 1.25 mm or 50 mils thick). Thus, Khanna's plaques were more than an order of magnitude thicker than the films of Murthy (the latter being similar to the thickness of the films of Mizuno and the present invention).

Murthy discloses that PCTFE films can have crystallinities ranging from 11% to 77% as determined by X-ray diffraction, the technique employed in the instant application and in Levy (see page 1255, right column). The crystallinity levels determined by X-ray diffraction depend on the thermal treatment of the sample (see page 1255, right column, under "Results").

Murthy also states that when determining crystallinity by DSC, one drawback is the crystallization of the polymer that occurs during heating of the sample (page 1259, right column), and also states that crystallization is observed using DSC between the  $T_g$  and  $T_m$  (page 1255, paragraph bridging left and right columns). Murthy discloses that the DSC crystallinities are consistently higher or lower than those determined by XRD (page 1258, left column).

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Thus, the analytical chemistry field recognized (per Murthy), after the publications of both Khanna and Choy, that a wide range of crystallinities exists in various PCTFE samples, and that all samples do not necessarily have to have crystallinity ranges mentioned in those prior publications. In addition, Murthy clearly states that the crystallinity levels determined by DSC are different from that determined by XRD.

It is therefore respectfully submitted that the basis of the rejection of the claims in the Final Rejection has been rebutted. That is, the Final Rejection is predicated on crystallinity levels no less than 15% (or as high as 50%) for articles that are quenched, whereas the analytical sciences field has recognized that crystallinities of at least as low as 11% have been reported for thin films. Thus, it is submitted that it cannot be concluded that inherently the film of Mizuno has high crystallinity because the plaques of Khanna had high crystallinities (as determined by DSC).

Rather, since Mizuno clearly states that the crystallinity of the films should be suppressed before stretching, it is submitted that one skilled in the art would recognize that Mizuno starts with an amorphous film rather than a crystalline film as claimed herein. This is more evident from the teachings of Levy that preceded Mizuno.

Accordingly, it is respectfully submitted that the claims are patentable over the combination of Mizuno and Khanna, assuming that such combination is proper. Applicant further submits that such combination is not proper, as Mizuno is dealing with a thin film and Khanna is dealing with a thick plaque.

Regarding Choy, it likewise teaches high crystallinity in a thick plaque after quenching, but this is because the sample is very thick compared to the thin films of Mizuno. It is respectfully submitted that the fact that Choy achieves high crystalline levels in his thick plaque does not mean that the same will occur in thin films. Indeed, Murthy shows that thin films of PCTFE polymers can have substantially lower



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crystallinities than those measured by Choy. Accordingly, it is submitted that one skilled in the art would not consider it proper to deduce from Choy that the thin film of Mizuno must have a high crystallinity before stretching.

It is therefore respectfully submitted that Choy is no more pertinent than is Khanna. One skilled in the art would not consider combining the teachings of Choy with Mizuno since substantially different structures are involved (a 60 mil plaque vs. a maximum 3.9 mil film). Even if it were proper to combine the teachings, it is respectfully submitted that the claimed invention would still not be shown since there is no suggestion that the film of Mizuno would have the crystallinity as claimed herein.

Moreover, it is pointed out that Mizuno describes the stretched PCTFE film as having a crystallinity of 15-75% (see column 3, lines 12-13. If the assumption in the Final Rejection is correct that the quenched film of Mizuno cannot have a crystallinity lower than 15-50%, then it must be asked how a crystallinity level of 15% is stated for the stretched film product of Mizuno. This is especially revealing since it is known that stretching increases the crystallinity level. Thus, to obtain a final crystallinity level of 15%, it is clear that the starting crystallinity level must be below that number, which means that the starting film must be substantially amorphous, if not completely amorphous.

In summary, it is submitted that claims 1 and 3-12 are indeed patentable over the proposed combination of Mizuno in view of Choy and Khanna for the reasons stated above.

With regard to the calculations of permeability set forth in the Final Rejection, it is respectfully pointed out that such calculations need to be normalized to a 1 mil film.

With regard to claim 3, it is further pointed out that since there is no suggestion of the broader range of crystallinity set forth in claim 1, there is certainly no suggestion of

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this preferred amount of crystallinity in the pre-stretched film of claim 3. Accordingly, claim 3 is submitted to be further patentable for this reason.

With regard to claim 10, it is respectfully submitted that this claim is further patentable over the proposed combination of references since there is no suggestion at all from the references that the stretched film would have a water vapor transmission rate of less than 20% of unoriented film. The Final Rejection recognizes that Mizuno is silent as to the 20% level of water vapor transmission rate, yet concludes that such an amount would have been obvious. Note that the 20% level claimed in claim 10 refers not to a 20% decrease but an amount which is no more than 20% of the water vapor transmission rate of the unstretched film. Since it can only be assumed that the rejection is speculating on a decrease in water vapor transmission rate without any supporting facts, then it is submitted that the rejection of claim 10 can only be sustained by improperly using Applicant's own disclosure against him. Therefore, it is submitted that claim 10 is clearly patentable over the combined references.

#### C. Claims 14-21 and 23-25

Claims 14-25 (sic) were rejected under 35 USC §103 over the same combination of references mentioned above, plus DeAntonis. The latter reference was cited for its disclosure of the use of a casting roll. It is pointed out that claim 22 was previously cancelled and it is understood that such claim was included in the above grouping inadvertently. The rejection of the remaining claims is respectfully traversed.

Although a casting roll for a PCTFE film is disclosed in DeAntonis, such reference utterly fails to provide the features missing in the other references. Even if the references were combined as suggested, there would still not be shown a process in which the film from the casting roll has a crystallinity within the claimed range.

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Therefore, it is respectfully submitted that claim 14 and its dependent claims are indeed patentable over the applied references for the same reasons as mentioned above.

Claim 23 which recites a preferred crystallinity range is submitted to be further patentable for the same reasons as claim 3.

In summary, Applicant respectfully submits that claims 14-21 and 23-25 are patentable over the combination of Mizuno in view of Choy, Khanna and DeAntonis.

#### D. Claims 28 and 29

Claims 28 and 29 were rejected under 35 USC §103 as unpatentable over the same combination of references used in the rejection of claims 14-21 and 23-25. This rejection is likewise respectfully traversed.

Claim 28 calls for an in-line process wherein the film is oriented without being wound up after casting. The rejection of this claim is on the same basis of claim 14, with the additional comment that the difference between a batch process and a continuous process is prima facie obvious. This rejection is likewise respectfully traversed.

An important advantage of the instant process is that the film can be cast and stretched in the same line, as opposed to winding up the film and transporting it to another area of a manufacturing plant where it is oriented. None of the cited references suggest such a process. It is respectfully submitted that the difference between the claimed process and the prior art process is not one of batch vs. continuous. In a "batch" process it is contemplated that a relatively small amount of material is manufactured by all of the manufacturing steps. The contrasting "continuous" process speeds up the batch process by not having to isolate the completed material that is produced in a batch process. In distinction thereto, the prior art process did not complete the entire process claimed herein. Rather, it stopped at the casting step and required a separate orienting

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step. The herein-claimed invention calls for the entire process to be completed, and completed without an intermediate step of winding up the film.

Therefore, it is not seen how the relationship between the claimed process and the prior art can properly be labeled a continuous vs. batch process. Moreover, it is respectfully submitted that the case cited in the Final Rejection cannot properly stand for the proposition that all continuous processes are obvious over a corresponding batch process, since the continuous process may have different operating conditions, etc.

It is also respectfully submitted that claim 28 is patentable for the same reasons as the preceding claims. With regard to claim 29, it was stated in the Final Rejection that it would have been prima facie obvious to optimize the draw ratio. However, there is no suggestion whatsoever of utilizing the draw ratio of claim 29, and it is submitted that the particular draw ratio and its results are not disclosed or suggested in applied prior art. Consequently, it is submitted that claim 29 is further patentable over the proposed combination of references.

#### E. Summary

In summary, it is respectfully submitted that claims 1, 3-12, 14-21, 23-25, 28 and 29 are patentable and should be allowed. Therefore, entry of this Amendment and allowance of the application are respectfully requested. Alternatively, entry of this Amendment for purposes of appeal is respectfully requested as there would be fewer issues on appeal.

#### III. Request for Withdrawal of Finality of Rejection

Applicant also respectfully requests withdrawal of the finality of the Final Rejection. It is stated at page 15 of the Final Rejection that Applicant's amendment necessitated the new ground(s) of rejection. This conclusion is respectfully traversed and

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is submitted to be in error. Applicant requests reconsideration of the finality of the rejection of the claims.

In the prior Amendment, claims 1 and 14 were amended to include a degree of crystallinity into these claims, rather than stating that the film was "crystalline". However, original claims 3 and 23 clearly stated a percentage crystallinity (a preferred range). Claims 1 and 14 merely expanded that range to what is disclosed in the specification. It is submitted that the mere inclusion in the independent claims of a percent crystallinity did not require the Office to conduct any further search or consideration, since the same issues are presented by original claims 3 and 23. Moreover, claims 1 and 14 previously recited that the film was in its crystalline state. The term "crystalline" is defined at page 5, lines 20-27 of the specification and the percentage amount is therein stated. Thus, including the percentage amount in the amended claims did not require an additional search or consideration by the Office.

The Choy and Khanna references are not being cited for their disclosure of the percent crystallinity in claims 1 and 14 as opposed to that of unamended claims 3 and 23. Indeed, the same basis is being used to reject the dependent claims as to reject the independent claims. Consequently, it is submitted that the amendments to claims 1 and 14 did not necessitate the citation of Choy and/or Khanna. What did in fact lead to their citation was Applicant's arguments concerning the deficiencies in the primary reference, Mizuno. However, there was no amendment that necessitated the citation of these secondary references.

Likewise, it is submitted that the addition of new claims 28 and 29 did not require the citation of either Choy or Khanna. Indeed, the rejection of these claims does not rely on any ground other than that stated with respect to claims 1 and 14. Since the degree of crystallinity was already an issue per original claims 3 and 23, it would not be correct to base a finality of a rejection on the grounds that claims 28 and 29 were added. Simply stated, these claims did not raise any issues to which Choy and/or Khanna were required

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to be cited. It is respectfully submitted that the secondary references should have been cited in the first Office Action. It is submitted that their citation in this second Office Action is not grounds for making the rejection final.

Under Section 706.07 (a) of the MPEP, a final rejection is not appropriate where a new ground of rejection is introduced which is not necessitated by an applicant's amendment of the claims. It is submitted that the foregoing analysis shows that this is the case in the instant situation, and that a final rejection of the claims is premature.

Accordingly, it is respectfully submitted that the finality of the rejection be withdrawn.

#### IV. CONCLUSION

For the above reasons, it is respectfully submitted that all of the claims in the application are patentable and should be allowed. Early notification to that effect is most respectfully solicited. Therefore, entry of this Amendment and allowance of the claims are respectfully requested. Should the rejections be maintained, then Applicant respectfully requests that the finality of the rejection be withdrawn. Alternatively, Applicant respectfully requests entry of this Amendment for purposes of appeal.

Attached is PTO Form 1449 which includes a citation of the Murthy article. It is respectfully requested that this document be made of record in the application.

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Should the Examiner believe that a discussion with Applicant's representative would in any way be of assistance, he is respectfully requested to telephone the undersigned.

Respectfully submitted,

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**Attachments**

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